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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,846	06/10/2002	Eliseo Quintanilla Almagro	Q-65077	1153

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,846

Applicant(s)

ALMAGRO ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-20 is/are allowed.
- 6) ☒ Claim(s) 8-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The preliminary amendment filed June 10, 2002 has been received and entered.
2. Claims 1-7 have been cancelled.
3. Claims 8-20 have been added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Sempere et al. (Immunology (December 1999), vol. 98, suppl. 1, pp. 105).

Applicant's claims are drawn towards a method of inhibiting the expression of adhesion molecules, inhibiting inflammation, and immuno-modulation using a water-soluble and a lipid-soluble extract from *Polypodium*.

Sempere teaches using a *Polypodium* extract, Anapsos, to modulate the expression of adhesion molecules. The extract modulates CD11a, CD11b, CD18, CD54, and CD6L and reduces inflammation. The reference does not specifically state that the Anapsos contains 118 mg of a water-soluble fraction and 2 mg of a lipid soluble-fraction; however, in applicant's specification, applicant has stated that Anapsos contains these fractions (see page 1, first paragraph of specification).

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Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

5. Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,601,829.

US '829 teaches modulating the immune system using 118 mg of a water soluble extract and 2 mg of a lipid soluble extract from *Polypodium* (see column 2, last paragraph and bottom of column 4).

6. Claims 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sempere et al. (Br. J. Clin. Pharmacol. (1997), vol. 43, no. 1, pp. 85-89).

Sempere teaches using Anapsos to reduce inflammation and modulate the immune system (see page 88). Sempere does not specifically teach that Anapsos inhibits the expression of adhesion molecules; however, adhesion molecules are an essential part of the inflammatory response. Since the reference teaches administering Anapsos to reduce inflammation, the method taught by the reference would inherently have the effect of reducing adhesion molecules.

7. Claims 8-16 are rejected. Claims 17-20 are free of the prior art and are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

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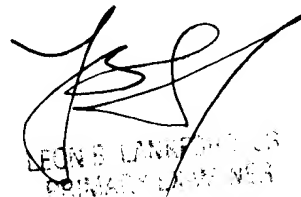
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC

August 27, 2002



LEON L. LANNING, JR.
ATTORNEY AT LAW